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Orchid Chemicals & Pharmaceuticals, Ltd., Orchid Healthcare and Orgenus Pharma, Inc.

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

SEPRACOR INC. and	)	
UNIVERSITY OF MASSACHUSETTS	)	
	)	
Plaintiffs,	)	Hon. Mary L. Cooper
	)	Case No. 07-CV-4623 (MLC) (TJB)
v.	)	
	)	<b>DEFENDANTS' ANSWER,</b>
ORCHID CHEMICALS &	)	<b>AFFIRMATIVE DEFENSES AND</b>
PHARMACEUTICALS LTD., ORCHID	)	<b>COUNTERCLAIM</b>
HEALTHCARE, and ORGENUS PHARMA,	)	
INC.,	)	
	)	
Defendants.	)	

Defendants Orchid Chemicals & Pharmaceuticals Ltd., Orchid Healthcare and Organus Pharma, Inc. (collectively "Defendants"), by and through their attorneys, hereby jointly respond to the complaint of plaintiffs Sepracor Inc. and University of Massachusetts (collectively "Plaintiffs"), as follows:

**Nature of the Action**

1. Defendants are without information or knowledge sufficient to admit or deny whether United States Patent Nos. 7,211,582 (the "582 Patent"), 7,214,683 (the "683 Patent") and 7,214,684 (the "684 Patent") are owned by Defendants, and therefore deny those allegations and the remaining allegations of paragraph 1 of the complaint.

**The Parties**

2. Defendants are without information or knowledge sufficient to admit or deny the allegations of paragraph 2, and therefore deny those allegations.

3. Defendants are without information or knowledge sufficient to admit or deny the allegations of paragraph 3, and therefore deny those allegations.

4. Defendants admit the allegations of paragraph 4.

5. Defendants admit that Defendant Orchid Healthcare is a division of Orchid Chemicals & Pharmaceuticals Ltd., having a place of business at Plot No. B3-B6 & B11-B14, Sipcot Industrial Park, Irungattukottai, Sriperumbudur (TK) – 602 105, Kancheepuram District, Tamil Nadu, India, but deny the remaining allegations of paragraph 5.

6. Defendants admit that Defendant Organus Pharma, Inc. is a New Jersey Corporation having a place of business at 116 Village Boulevard, Suite 200, Princeton, New Jersey, 08540, but deny the remaining allegations of paragraph 6.

7. Defendants admit that the complaint refers to Orchid Chemicals & Pharmaceuticals, Ltd. and Orchid Healthcare collectively as Orchid, as stated in paragraph 7.

8. Defendants admit that Orchid is in the business of manufacturing generic pharmaceutical products, but deny the remaining allegations of paragraph 8.

9. Defendants admit that they filed with the FDA, pursuant to 21 U.S.C. §355(j), ANDA No. 78-356 concerning a generic drug in competition with Desloratadine Orally Disintegrating Tablets, 2.5 mg and 5 mg, which Schering Corporation markets under the brand name Clarinex®, and ANDA No. 78-357 concerning a generic drug in competition with Desloratadine Tablets, 5 mg, which Schering Corporation markets under the brand name Clarinex®, but deny the remaining allegations of paragraph 9.

10. Defendants admit that they are seeking FDA approval to market generic products in the United States, but deny the remaining allegations of paragraph 10.

#### **Jurisdiction and Venue**

11. Defendants admit the allegations of paragraph 11.

12. Defendants admit the allegations of paragraph 12.

13. Defendants admit that this court has personal jurisdiction over Orchid and that Orchid markets and sells generic drugs throughout the United States and in this judicial district, but deny the remaining allegations of paragraph 13.

14. Defendants admit that this court has personal jurisdiction over Orchid and that Orchid is a defendant and has filed certain counterclaims in *Schering Corporation v. Zyduk Pharmaceuticals, USA, Inc. et al.*, D.N.J., Civil Action No. 3:06-4715 (MLC) (TJB), but deny the remaining allegations of paragraph 14.

15. Defendants admit the allegations of paragraph 15.

**The Patents in Suit and the Clarinex® Drug Products**

16. Defendants admit that a copy of the 582 Patent having an issue date of May 1, 2007, is attached as Exhibit A to the complaint; are without information or knowledge sufficient to admit or deny whether Plaintiffs are the assignees of the entire right, title and interest in the 582 Patent, and therefore deny those allegations; and deny the remaining allegations of paragraph 16.

17. Defendants admit that a copy of the 683 Patent having an issue date of May 8, 2007, is attached as Exhibit B to the complaint; are without information or knowledge sufficient to admit or deny whether Plaintiffs are the assignees of the entire right, title and interest in the 683 Patent, and therefore deny those allegations; and deny the remaining allegations of paragraph 17.

18. Defendants admit that a copy of the 684 Patent having an issue date of May 8, 2007 is attached as Exhibit C to the complaint; are without information or knowledge sufficient to admit or deny whether Plaintiffs are the assignees of the entire right, title and interest in the 684 Patent, and therefore deny those allegations; and deny the remaining allegations of paragraph 18.

19. Defendants admit that the 582, 683 and 684 Patents are identified in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") in association with 5 milligram Desloratadine Tablets, which are sold as a commercial product under the trade name Clarinex®, and 2.5 and 5 milligram Desloratadine Orally Disintegrating Tablets, which are sold as a commercial product under the trade name Clarinex® Reditabs®, but deny the remaining allegations of paragraph 19.

**Acts Giving Rise to this Action**

20. Defendants admit that Plaintiffs Sepracor Inc. ("Sepracor") and University of Massachusetts ("UMass") received a letter from Orchid, dated August 13, 2007, notifying them that Orchid had filed with the FDA, pursuant to 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §355(j)), ANDA No. 78-356 to obtain approval to engage in the commercial manufacture, use, or sale of a generic drug in competition with Desloratadine Orally Disintegrating Tablets, 2.5 mg and 5 mg, which Schering Corporation markets under the brand name Clarinex®, but deny the remaining allegations of paragraph 20.

21. Defendants admit that Plaintiffs Sepracor and UMass received a second letter from Orchid, dated August 13, 2007, notifying them that Orchid had filed with the FDA, pursuant to 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §355(j)), ANDA No. 78-357 to obtain approval to engage in the commercial manufacture, use, or sale of a generic drug in competition with Desloratadine Tablets, 5 mg, which Schering Corporation markets under the brand name Clarinex®, but deny the remaining allegations of paragraph 21.

22. Defendants admit that they are seeking FDA approval to engage in the commercial manufacture, use, or sale of a generic drug in competition with Desloratadine Orally Disintegrating Tablets, 2.5 mg and 5 mg, which Schering Corporation markets under the brand name Clarinex®, and to engage in the commercial manufacture, use, or sale of a generic drug in competition with Desloratadine Tablets, 5 mg, which Schering Corporation markets under the brand name Clarinex®, but deny the remaining allegations of paragraph 22.

23. Defendants admit the allegations of paragraph 23.

24. Defendants deny the allegations of paragraph 24.

25. Defendants admit that ANDA No. 78-356 concerns a generic drug in competition with Desloratadine Orally Disintegrating Tablets, 2.5 mg and 5 mg, which Schering Corporation markets under the brand name Clarinex®, and ANDA No. 78-357 concerns a generic drug in competition with Desloratadine Tablets, 5 mg, which Schering Corporation markets under the brand name Clarinex®, but deny the remaining allegations of paragraph 25.

26. Defendants need not respond to the allegations of paragraph 26 which purport to state conclusions of law as to which no response is necessary.

### **Count I**

27. Defendants repeat their answers to the allegations of paragraphs 1 through 26 of the complaint as if fully set forth at length here.

28. Defendants deny the allegations of paragraph 28.

29. Defendants deny the allegations of paragraph 29.

30. Defendants deny the allegations of paragraph 30.

31. Defendants deny the allegations of paragraph 31.

32. Defendants deny the allegations of paragraph 32.

### **Count II**

33. Defendants repeat their answers to the allegations of paragraphs 1 through 32 of the complaint as if fully set forth at length here.

34. Defendants deny the allegations of paragraph 34.

35. Defendants deny the allegations of paragraph 35.

36. Defendants deny the allegations of paragraph 36.

37. Defendants deny the allegations of paragraph 37.

38. Defendants deny the allegations of paragraph 38.

**Count III**

39. Defendants repeat their answers to the allegations of paragraphs 1 through 38 of the complaint as if fully set forth at length here.

40. Defendants deny the allegations of paragraph 40.

41. Defendants deny the allegations of paragraph 41.

42. Defendants deny the allegations of paragraph 42.

43. Defendants deny the allegations of paragraph 43.

44. Defendants deny the allegations of paragraph 44.

**First Affirmative Defense**

The complaint fails to state a claim upon which relief can be granted.

**Second Affirmative Defense**

One or more claims of the 582, 683 and 684 patents are invalid for failing to satisfy one or more requirements of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§102, 103, and/or 112.

**Third Affirmative Defense**

Defendants do not infringe, have not infringed, are not inducing, contributing to, or cooperating in the infringement of, and have not induced, contributed to, or cooperated in the infringement of, the 582, 683 and 684 patents.

**Fourth Affirmative Defense**

The complaint should be dismissed because the 582, 683 and 684 patents are not properly listed in the Orange Book.

WHEREFORE, Defendants Orchid Chemicals & Pharmaceuticals Ltd., Orchid Healthcare, and Orgenus Pharma, Inc. demand judgment in their favor, dismissing the complaint

with prejudice, together with costs of suit, and such other and further relief as the Court may deem just and appropriate.

### **Counterclaim**

Defendants/counterclaimants Orchid Chemicals & Pharmaceuticals Ltd., Orchid Healthcare, and Orgenus Pharma, Inc., as and for their counterclaim against Plaintiffs, state and allege as follows:

### **Nature of the Action**

1. This counterclaim seeks a declaratory judgment of non-infringement and invalidity of the 582, 683 and 684 Patents asserted by Plaintiffs in this action. Defendants seek judgment under the patent laws of the United States, 35 U.S.C. § 101, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. § 2201 and 2202.

### **The Parties**

2. Defendant/counterclaimant Orchid Chemicals & Pharmaceuticals Ltd. is a public limited liability company organized under the laws of India, which maintains its principal place of business at Orchid Towers, No. 313, Valluvar Kottam Road, Nungambakkam, Chennai – 600 034, Tamil Nadu, India.

3. Defendant/counterclaimant Orchid Healthcare is an unincorporated division of Orchid Chemicals & Pharmaceuticals Ltd., which maintains a place of business at Plot Nos. B3-B6 and B11-B-14, SIPCOT Industrial Park, Irungattukottai, Kancheepuram District – 602 105, India.

4. Defendant/counterclaimant Orgenus Pharma Inc. is a corporation organized under the laws of New Jersey and maintains its principal place of business at 116 Village Boulevard, Suite 200, Princeton, New Jersey 08540.



5. Plaintiff Sepracor Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 84 Waterford Drive, Marlborough, Massachusetts 01752.

6. Plaintiff University of Massachusetts is a public institution of higher education of the Commonwealth of Massachusetts, having a place of business at 55 Lake Avenue North, Worcester, Massachusetts 01655.

### **Jurisdiction and Venue**

7. This Court has subject matter jurisdiction over this amended counterclaim pursuant to 28 U.S.C. §§ 1331 and 1338(a), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, justiciable controversy exists within this jurisdiction regarding, *inter alia*, the validity of the 582, 683 and 684 patents and the technical act of infringement of Defendants-counterclaimants' generic drugs that would compete with Desloratadine Orally Disintegrating Tablets, 2.5 mg and 5 mg, and Desloratadine Tablets, 5 mg, as evidenced by the filing of Plaintiffs' complaint and Plaintiffs' listing of the 582, 683 and 684 patents in the Orange Book in association with 5 milligram Desloratadine Tablets and 2.5 and 5 milligram Desloratadine Orally Disintegrating Tablets.

8. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(d).

### **COUNT I (Non-Infringement)**

9. Defendants/counterclaimants do not infringe and have not infringed the 582, 683 or 684 patents directly, contributorily or by inducement.

**COUNT II**  
**(Invalidity)**

10. One or more of the claims of the 582, 683 and 684 patents are invalid because they fail to satisfy one or more of the conditions for patentability under Title 35 of the United States Code, including one or more of the following: 35 U.S.C. §§102, 103, and/or 112.

WHEREFORE, Defendants/counterclaimants respectfully pray for judgment:

a. Declaring the 582, 683 and 684 patents invalid and/or not infringed by Defendants-counterclaimants;

b. Awarding Defendants-counterclaimants such other and further relief as the Court may deem just and appropriate.

Dated: December 31, 2007

s/ Bradley L. Mitchell  
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Healthcare and Orgenus Pharma, Inc.

**CERTIFICATE OF SERVICE**

I hereby certify that the foregoing Defendants' Answer, Affirmative Defenses And Counterclaim was served on this 31st day of December, 2007, on the following by means of the Court's Notice of Electronic Filing:

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